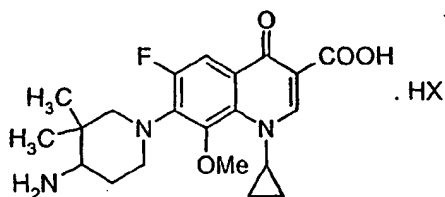


We claim:

1. A polymorph of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride, R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride, S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride and racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate, R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate, S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate having the formula I and II respectively



Formula I    HX = HCl  
Formula II    HX = CH<sub>3</sub>SO<sub>3</sub>H

wherein said polymorph is selected from the group comprising

- a) a racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern  
(2 $\theta$ ): 5.32 $\pm$ 0.2°, 5.68 $\pm$ 0.2°, 9.42 $\pm$ 0.2°, 10.06 $\pm$ 0.2°, 10.40 $\pm$ 0.2°, 11.40 $\pm$ 0.2°, 11.78 $\pm$ 0.2°, 12.98 $\pm$ 0.2°, 13.74 $\pm$ 0.2°, 14.38 $\pm$ 0.2°, 14.66 $\pm$ 0.2°, 16.02 $\pm$ 0.2°, 22.52 $\pm$ 0.2°, 23.74 $\pm$ 0.2°, 24.48 $\pm$ 0.2°, 25.22 $\pm$ 0.2°, 27.36 $\pm$ 0.2°, 28.74 $\pm$ 0.2°, 31.28 $\pm$ 0.2°, 31.72  $\pm$ 0.2°.

- b) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern  
(2 $\theta$ ): 5.34  $\pm$  0.2°, 5.70  $\pm$  0.2°, 9.46  $\pm$  0.2°, 10.08  $\pm$  0.2°, 10.44  $\pm$  0.2°, 11.42  $\pm$  0.2°, 11.82  $\pm$  0.2°, 12.86  $\pm$  0.2°, 13.62  $\pm$  0.2°, 14.26  $\pm$  0.2°, 14.72  $\pm$  0.2°, 16.08  $\pm$  0.2°, 22.16  $\pm$  0.2°, 23.68  $\pm$  0.2°, 24.18  $\pm$  0.2°, 24.86  $\pm$  0.2°, 25.98  $\pm$  0.2°, 27.04  $\pm$  0.2°, 28.84  $\pm$  0.2°, 31.56  $\pm$  0.2°, 31.84  $\pm$  0.2°.
- c) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-3 exhibiting the following X-ray diffraction pattern  
(2 $\theta$ ): 7.04  $\pm$  0.2°, 7.70  $\pm$  0.2°, 8.06  $\pm$  0.2°, 12.34  $\pm$  0.2°, 12.78  $\pm$  0.2°, 13.64  $\pm$  0.2°, 15.40  $\pm$  0.2°, 16.14  $\pm$  0.2°, 18.62  $\pm$  0.2°, 19.40  $\pm$  0.2°, 20.64  $\pm$  0.2°, 21.84  $\pm$  0.2°, 23.22  $\pm$  0.2°, 26.80  $\pm$  0.2°, 27.88  $\pm$  0.2°, 29.86  $\pm$  0.2°, 32.30  $\pm$  0.2°, 33.36  $\pm$  0.2°, 37.02  $\pm$  0.2°, 39.24  $\pm$  0.2°.
- d) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride polymorph A-4 exhibiting the following X-ray diffraction pattern  
(2 $\theta$ ): 5.34  $\pm$  0.2°, 5.68  $\pm$  0.2°, 9.48  $\pm$  0.2°, 10.08  $\pm$  0.2°, 10.44  $\pm$  0.2°, 11.42  $\pm$  0.2°, 11.84  $\pm$  0.2°, 12.86  $\pm$  0.2°, 13.62  $\pm$  0.2°, 14.24  $\pm$  0.2°, 14.74  $\pm$  0.2°, 16.08  $\pm$  0.2°, 22.16  $\pm$  0.2°, 24.14  $\pm$  0.2°, 24.82  $\pm$  0.2°, 25.94  $\pm$  0.2°, 27.02  $\pm$  0.2°, 28.84  $\pm$  0.2°, 31.82  $\pm$  0.2°.
- e) a racemic-( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern  
(2 $\theta$ ): 5.80  $\pm$  0.2°, 8.08  $\pm$  0.2°, 9.08  $\pm$  0.2°, 12.92  $\pm$  0.2°, 14.70  $\pm$  0.2°, 16.48  $\pm$  0.2°, 17.40  $\pm$  0.2°, 18.36  $\pm$  0.2°, 18.74  $\pm$  0.2°, 19.60  $\pm$  0.2°, 20.44  $\pm$  0.2°, 20.94  $\pm$  0.2°, 21.50  $\pm$  0.2°, 22.80  $\pm$  0.2°, 23.28  $\pm$  0.2°, 23.84  $\pm$  0.2°, 24.36  $\pm$  0.2°, 25.50  $\pm$  0.2°, 26.00  $\pm$  0.2°, 26.78  $\pm$  0.2°, 27.24  $\pm$  0.2°, 29.22  $\pm$  0.2°, 30.66  $\pm$  0.2°, 37.58  $\pm$  0.2°.

- f) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern

(2 $\theta$ ):  $5.74 \pm 0.2^\circ$ ,  $8.02 \pm 0.2^\circ$ ,  $9.02 \pm 0.2^\circ$ ,  $12.84 \pm 0.2^\circ$ ,  $14.74 \pm 0.2^\circ$ ,  $16.46 \pm 0.2^\circ$ ,  
 $17.32 \pm 0.2^\circ$ ,  $18.38 \pm 0.2^\circ$ ,  $19.58 \pm 0.2^\circ$ ,  $20.38 \pm 0.2^\circ$ ,  $20.92 \pm 0.2^\circ$ ,  $21.48 \pm 0.2^\circ$ ,  
 $22.80 \pm 0.2^\circ$ ,  $23.80 \pm 0.2^\circ$ ,  $24.28 \pm 0.2^\circ$ ,  $25.62 \pm 0.2^\circ$ ,  $26.88 \pm 0.2^\circ$ ,  $27.32 \pm 0.2^\circ$ ,  
 $28.20 \pm 0.2^\circ$ ,  $29.16 \pm 0.2^\circ$ ,  $30.68 \pm 0.2^\circ$ .

- g) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-1 exhibiting the following X-ray diffraction pattern

X-ray powder diffraction (2 $\theta$ ):  $8.02 \pm 0.2^\circ$ ,  $12.84 \pm 0.2^\circ$ ,  $14.70 \pm 0.2^\circ$ ,  $16.44 \pm 0.2^\circ$ ,  
 $17.30 \pm 0.2^\circ$ ,  $19.56 \pm 0.2^\circ$ ,  $20.90 \pm 0.2^\circ$ ,  $21.46 \pm 0.2^\circ$ ,  $23.76 \pm 0.2^\circ$ ,  $25.56 \pm 0.2^\circ$ ,  
 $27.30 \pm 0.2^\circ$ ,  $30.66 \pm 0.2^\circ$ ,  $37.46 \pm 0.2^\circ$ .

- h) a racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern

(2 $\theta$ ):  $9.40 \pm 0.2^\circ$ ,  $9.94$ ,  $10.74 \pm 0.2^\circ$ ,  $12.32 \pm 0.2^\circ$ ,  $12.98 \pm 0.2^\circ$ ,  $14.02 \pm 0.2^\circ$ ,  $15.72 \pm 0.2^\circ$ ,  
 $16.92 \pm 0.2^\circ$ ,  $18.84 \pm 0.2^\circ$ ,  $19.38 \pm 0.2^\circ$ ,  $20.52 \pm 0.2^\circ$ ,  $21.20 \pm 0.2^\circ$ ,  $22.80$ ,  
 $22.96 \pm 0.2^\circ$ ,  $24.64 \pm 0.2^\circ$ ,  $25.54 \pm 0.2^\circ$ ,  $28.38 \pm 0.2^\circ$ ,  $29.92 \pm 0.2^\circ$ ,  $30.72 \pm 0.2^\circ$ ,  
 $35.92$ ,  $37.88 \pm 0.2^\circ$ .

- i) a R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern

(2 $\theta$ ):  $8.04 \pm 0.2^\circ$ ,  $9.36 \pm 0.2^\circ$ ,  $10.06 \pm 0.2^\circ$ ,  $10.84 \pm 0.2^\circ$ ,  $12.24 \pm 0.2^\circ$ ,  $12.88 \pm 0.2^\circ$ ,  
 $13.94 \pm 0.2^\circ$ ,  $15.26 \pm 0.2^\circ$ ,  $15.76 \pm 0.2^\circ$ ,  $16.82 \pm 0.2^\circ$ ,  $17.16 \pm 0.2^\circ$ ,  $18.78 \pm 0.2^\circ$ ,  
 $19.62 \pm 0.2^\circ$ ,  $20.42 \pm 0.2^\circ$ ,  $21.22 \pm 0.2^\circ$ ,  $22.30 \pm 0.2^\circ$ ,  $23.16 \pm 0.2^\circ$ ,  $24.26 \pm 0.2^\circ$ ,  
 $24.62 \pm 0.2^\circ$ ,  $25.54 \pm 0.2^\circ$ ,  $28.38 \pm 0.2^\circ$ ,  $30.00 \pm 0.2^\circ$ ,  $30.84 \pm 0.2^\circ$ ,  $38.18 \pm 0.2^\circ$ .

- j) a S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate polymorph B-2 exhibiting the following X-ray diffraction pattern

(2 $\theta$ ): 9.38 $\pm$  0.2°, 10.04 $\pm$  0.2°, 12.28 $\pm$  0.2°, 12.94 $\pm$  0.2°, 13.98 $\pm$  0.2°, 15.78 $\pm$  0.2°, 16.86 $\pm$  0.2°, 18.80 $\pm$  0.2°, 19.62 $\pm$  0.2°, 21.24 $\pm$  0.2°, 22.32 $\pm$  0.2°, 23.18 $\pm$  0.2°, 24.64 $\pm$  0.2°, 25.56 $\pm$  0.2°, 28.44 $\pm$  0.2°, 30.02 $\pm$  0.2°, 30.90 $\pm$  0.2°, 39.74 $\pm$  0.2°.

2. The compound according to claim 1 corresponding to polymorph A-3 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
3. The compound according to claim 1 corresponding to polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
4. The compound according to claim 1 corresponding to polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
5. The compound according to claim 1 corresponding to polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
6. The compound according to claim 1 corresponding to polymorph B-1 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
7. The compound according to claim 1 corresponding to polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
8. The compound according to claim 1 corresponding to polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.

9. The compound according to claim 1 corresponding to polymorph B-2 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
10. The compound according to claim 1 corresponding to polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
11. The compound according to claim 1 corresponding to polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate.
12. A process for preparing polymorph A-3 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern
- (2 $\theta$ ):  $5.32 \pm 0.2^\circ$ ,  $5.68 \pm 0.2^\circ$ ,  $9.42 \pm 0.2^\circ$ ,  $10.06 \pm 0.2^\circ$ ,  $10.40 \pm 0.2^\circ$ ,  $11.40 \pm 0.2^\circ$ ,  $11.78 \pm 0.2^\circ$ ,  $12.98 \pm 0.2^\circ$ ,  $13.74 \pm 0.2^\circ$ ,  $14.38 \pm 0.2^\circ$ ,  $14.66 \pm 0.2^\circ$ ,  $16.02 \pm 0.2^\circ$ ,  $22.52 \pm 0.2^\circ$ ,  $23.74 \pm 0.2^\circ$ ,  $24.48 \pm 0.2^\circ$ ,  $25.22 \pm 0.2^\circ$ ,  $27.36 \pm 0.2^\circ$ ,  $28.74 \pm 0.2^\circ$ ,  $31.28 \pm 0.2^\circ$ ,  $31.72 \pm 0.2^\circ$ .
- which process comprises the steps of
- a) drying polymorphic A-1 form of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably  $130^\circ\text{C}$  upto  $150^\circ\text{C}$ , optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
- b) recovering the polymorphic form A-3 as a crystalline solid.
13. A process for preparing polymorph A-3 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, exhibiting the X-ray diffraction pattern
- (2 $\theta$ ):  $5.32 \pm 0.2^\circ$ ,  $5.68 \pm 0.2^\circ$ ,  $9.42 \pm 0.2^\circ$ ,  $10.06 \pm 0.2^\circ$ ,  $10.40 \pm 0.2^\circ$ ,  $11.40 \pm 0.2^\circ$ ,  $11.78 \pm 0.2^\circ$ ,  $12.98 \pm 0.2^\circ$ ,  $13.74 \pm 0.2^\circ$ ,  $14.38 \pm 0.2^\circ$ ,  $14.66 \pm 0.2^\circ$ ,  $16.02 \pm 0.2^\circ$ ,  $22.52 \pm 0.2^\circ$ ,  $23.74 \pm 0.2^\circ$ ,  $24.48 \pm 0.2^\circ$ ,  $25.22 \pm 0.2^\circ$ ,  $27.36 \pm 0.2^\circ$ ,  $28.74 \pm 0.2^\circ$ ,  $31.28 \pm 0.2^\circ$ ,  $31.72 \pm 0.2^\circ$ .

which process comprises the steps of :

- a) drying polymorphic A-2 form of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C, optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
- b) recovering the polymorphic form A-3 as a crystalline solid.

14. A process for preparing polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern

(2 $\theta$ ): 5.34  $\pm$  0.2°, 5.70  $\pm$  0.2°, 9.46  $\pm$  0.2°, 10.08  $\pm$  0.2°, 10.44  $\pm$  0.2°, 11.42  $\pm$  0.2°, 11.82  $\pm$  0.2°, 12.86  $\pm$  0.2°, 13.62  $\pm$  0.2°, 14.26  $\pm$  0.2°, 14.72  $\pm$  0.2°, 16.08  $\pm$  0.2°, 22.16  $\pm$  0.2°, 23.68  $\pm$  0.2°, 24.18  $\pm$  0.2°, 24.86  $\pm$  0.2°, 25.98  $\pm$  0.2°, 27.04  $\pm$  0.2°, 28.84  $\pm$  0.2°, 31.56  $\pm$  0.2°, 31.84  $\pm$  0.2°.

which process comprises the steps of

- a. drying polymorphic A-1 form of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C, optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and
- b. recovering the polymorphic form A-3 as a crystalline solid.

15. A process for preparing polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern

(2 $\theta$ ): 5.34  $\pm$  0.2°, 5.70  $\pm$  0.2°, 9.46  $\pm$  0.2°, 10.08  $\pm$  0.2°, 10.44  $\pm$  0.2°, 11.42  $\pm$  0.2°, 11.82  $\pm$  0.2°, 12.86  $\pm$  0.2°, 13.62  $\pm$  0.2°, 14.26  $\pm$  0.2°, 14.72  $\pm$  0.2°, 16.08  $\pm$  0.2°, 22.16  $\pm$  0.2°, 23.68  $\pm$  0.2°, 24.18  $\pm$  0.2°, 24.86  $\pm$  0.2°, 25.98  $\pm$  0.2°, 27.04  $\pm$  0.2°, 28.84  $\pm$  0.2°, 31.56  $\pm$  0.2°, 31.84  $\pm$  0.2°.

which process comprises the steps of

- a) drying polymorphic A-2 form of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably 130°C upto 150°C,

optionally under reduced pressure sufficient to effect transformation to polymorphic form A-3; and

b) recovering the polymorphic form A-3 as a crystalline solid.

- 5 16. A process for preparing polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, exhibiting the X-ray diffraction pattern
- (2 $\theta$ ):  $5.34 \pm 0.2^\circ$ ,  $5.68 \pm 0.2^\circ$ ,  $9.48 \pm 0.2^\circ$ ,  $10.08 \pm 0.2^\circ$ ,  $10.44 \pm 0.2^\circ$ ,  $11.42 \pm 0.2^\circ$ ,  $11.84 \pm 0.2^\circ$ ,  $12.86 \pm 0.2^\circ$ ,  $13.62 \pm 0.2^\circ$ ,  $14.24 \pm 0.2^\circ$ ,  $14.74 \pm 0.2^\circ$ ,  $16.08 \pm 0.2^\circ$ ,  $22.16 \pm 0.2^\circ$ ,  $24.14 \pm 0.2^\circ$ ,  $24.82 \pm 0.2^\circ$ ,  $25.94 \pm 0.2^\circ$ ,  $27.02 \pm 0.2^\circ$ ,  $28.84 \pm 0.2^\circ$ ,  $31.82 \pm 0.2^\circ$ .

which process comprises the steps of:

- 15 a) drying polymorphic A-3 form of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride at an elevated temperature, preferably  $130^\circ\text{C}$  upto  $150^\circ\text{C}$ , optionally under reduced pressure sufficient to effect transformation to polymorphic form A-4; and
- b) recovering the polymorphic form A-4 as a crystalline solid.

- 20 17. A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern
- (2 $\theta$ ):  $7.04 \pm 0.2^\circ$ ,  $7.70 \pm 0.2^\circ$ ,  $8.06 \pm 0.2^\circ$ ,  $12.34 \pm 0.2^\circ$ ,  $12.78 \pm 0.2^\circ$ ,  $13.64 \pm 0.2^\circ$ ,  $15.40 \pm 0.2^\circ$ ,  $16.14 \pm 0.2^\circ$ ,  $18.62 \pm 0.2^\circ$ ,  $19.40 \pm 0.2^\circ$ ,  $20.64 \pm 0.2^\circ$ ,  $21.84 \pm 0.2^\circ$ ,  $23.22 \pm 0.2^\circ$ ,  $26.80 \pm 0.2^\circ$ ,  $27.88 \pm 0.2^\circ$ ,  $29.86 \pm 0.2^\circ$ ,  $32.30 \pm 0.2^\circ$ ,  $33.36 \pm 0.2^\circ$ ,  $37.02 \pm 0.2^\circ$ ,  $39.24 \pm 0.2^\circ$ .

25 which process comprises the steps of

- a) suspending or dissolving polymorphic form A-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
- b) stirring the mixture to form a suspension or a solution followed by adding a water-miscible organic solvent;
- 30 c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtering; and
- d) drying resultant crystals to constant weight to provide the polymorph A-3.

18. A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride exhibiting the X-ray diffraction pattern

(2 $\theta$ ): 7.04 $\pm$  0.2°, 7.70 $\pm$  0.2°, 8.06 $\pm$  0.2°, 12.34 $\pm$  0.2°, 12.78 $\pm$  0.2°, 13.64 $\pm$  0.2°, 15.40 $\pm$  0.2°, 16.14 $\pm$  0.2°, 18.62 $\pm$  0.2°, 19.40 $\pm$  0.2°, 20.64 $\pm$  0.2°, 21.84 $\pm$  0.2°, 23.22 $\pm$  0.2°, 26.80 $\pm$  0.2°, 27.88 $\pm$  0.2°, 29.86 $\pm$  0.2°, 32.30 $\pm$  0.2°, 33.36 $\pm$  0.2°, 37.02 $\pm$  0.2°, 39.24 $\pm$  0.2°.

which process comprises the steps of:

- a) suspending or dissolving polymorphic form A-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
- b) adding a water-miscible organic solvent and stirring resulting mixture for a sufficient period of time to effect the transformation completely to polymorphic form A-3;
- c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtering; and
- d) drying the resultant crystals to a constant weight to yield the product A-3..

19. A process for preparing polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride, from said polymorphs A-1 or A-2 or A-4 which process comprises

- a) suspending or dissolving polymorphic form A-1 or A-2 or A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride in water, if necessary by heating;
- b) stirring the mixture at that temperature to form a suspension or a solution followed by adding a water-miscible organic solvent;
- c) recovering the polymorphic form A-3 as a crystal upon cooling the solution and filtrating;
- d) drying the resultant crystals to a constant weight to yield the product of the invention.

20. A process for preparing polymorph B-1 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises



- 5
- a) suspending or dissolving racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
  - b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;
  - c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
  - d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
  - 10 e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.

21. A process for preparing polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- 15
- a) suspending or dissolving R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
  - b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;
  - 20 c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
  - d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
  - 25 e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.

22. A process for preparing polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises

- 30
- a) suspending or dissolving (-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid in a suitable organic solvent to form a suspension/solution;
  - b) heating the suspension/solution and adding methane sulfonic acid at the elevated temperature;

- c) heating the reaction mixture at elevated temperature sufficient to effect transformation to the mesylate polymorphic form B-1;
- d) recovering the polymorphic form B-1 as a crystal upon cooling the solution and filtering;
- 5 e) drying crystals to a constant weight to yield the polymorph B-1 of the invention.
23. A process for preparing polymorph B-2 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises
- 10 a) dissolving crystalline polymorphic form B-1 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate in water by heating to form a solution;
- b) cooling the solution and adding an aqueous-miscible organic solvent;
- c) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- 15 d) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- e) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.
- 20 24. A process for preparing polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises
- a) dissolving crystalline polymorphic form B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-
- 25 carboxylic acid mesylate in water by heating to form a solution;
- b) cooling the solution and adding an aqueous-miscible organic solvent;
- c) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- d) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- 30 e) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.

- 5
- f) A process for preparing polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate, which comprises
- g) dissolving crystalline polymorphic form B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid mesylate in water by heating to form a solution;
- h) cooling the solution and adding an aqueous-miscible organic solvent;
- i) allowing the reaction mixture to stand for a sufficient time to effect transformation to polymorphic form B-2,
- 10 j) recovering the polymorphic form B-2 as a crystal upon cooling and filtering;
- k) drying resultant crystals to a constant weight to yield the polymorph B-2 of the invention.
- 15 25. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of the compound of claim 1.
- 20 26. The method of claim 25 wherein said compound is polymorph A-3 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
27. The method of claim 25 wherein said compound is polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
- 25 28. The method of claim 25 wherein said compound is polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.
- 30 29. The method of claim 25 wherein said compound is polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline-3-carboxylic acid hydrochloride.

30. The method of claim 25 wherein said compound is polymorph B-1 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
- 5 31. The method of claim 25 wherein said compound is polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
32. The method of claim 25 wherein said compound is polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
- 10 33. The method of claim 25 wherein said compound is polymorph B-2 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
- 15 34. The method of claim 25 wherein said compound is polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
- 20 35. The method of claim 25 wherein said compound is polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid mesylate.
- 25 36. A pharmaceutical composition for treating bacterial infection in a mammal comprising an effective amount of the compound of claim 1 and a pharmaceutically acceptable carrier.
37. The composition of claim 36 wherein said compound is polymorph A-3 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride.
- 30 38. The composition of claim 36 wherein said compound is polymorph A-3 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxo-quinoline -3-carboxylic acid hydrochloride.

39. The composition of claim 36 wherein said compound is polymorph A-3 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid hydrochloride.
- 5 40. The composition of claim 36 wherein said compound is polymorph A-4 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid hydrochloride.
- 10 41. The composition of claim 36 wherein said compound is polymorph B-1 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate.
- 15 42. The composition of claim 36 wherein said compound is polymorph B-1 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate.
- 20 43. The composition of claim 36 wherein said compound is polymorph B-1 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate.
- 25 44. The composition of claim 36 wherein said compound is polymorph B-2 of racemic ( $\pm$ )-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate.
- 30 45. The composition of claim 36 wherein said compound is polymorph B-2 of R-(+)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate.
46. The composition of claim 36 wherein said compound is polymorph B-2 of S-(-)-1-cyclopropyl-6-fluoro-8-methoxy-7-(4-amino-3,3-dimethylpiperidin-1-yl)-1,4-dihydro-4-oxoquinoline -3-carboxylic acid mesylate. 47. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 36.

47. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 37.
- 5 48. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 38.
49. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 39.
- 10 50. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 40.
51. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 41.
- 15 52. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 42.
53. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 43.
- 20 54. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to claim 44.
55. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 45.
- 25 56. A method for treating bacterial infection in a mammal which comprises administering to said mammal an effective amount of a composition according to 46.
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